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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/804,954	03/19/2004	Marise S. Gottlieb		8077

7590 05/09/2006

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215 Chestnut Hill Road
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EXAMINER

CORDERO GARCIA, MARCELA M

ART UNIT	PAPER NUMBER
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1654

DATE MAILED: 05/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/804,954	Applicant(s) GOTTLIEB, MARISE S.	
	Examiner Marcela M. Cordero Garcia	Art Unit 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-18 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-7, drawn to a method for controlling chronic inflammation in an individual, classified, e.g., in class 424, subclass 93.7.
- II. Claims 8-9, drawn to a method for controlling elevated blood glucose level in an individual, classified, e.g., in class 514, subclass 18.
- III. Claims 10-13, drawn to a method for preventing chronic inflammation due to the presence of or potential exposure to a pathogen, environmental particulates or environmental toxins, classified, e.g., in class 514, subclass 19.
- IV. Claims 14-16, drawn to a method for mitigating a symptom in a patient, said symptom characteristic of an inflammation-related metabolic disturbance, classified, e.g., in class 514, subclass 19.
- V. Claim 17, drawn to a method for deferring the progression of a patient from the Metabolic Syndrome, classified, e.g., in class 514, subclass 18.
- VI. Claim 18, drawn to a method for preventing or mitigating development of inflammation-related sequelae of exposure of a person to liquids or vapors containing organic solvents or hydrocarbon fuels, classified, e.g., in class 514, subclass 19.

The inventions are distinct, each from the other because of the following reasons: The methods of Groups I-VI are directed to different inventions which are not connected in design, operation, or effect. These methods are independent since they are not disclosed as capable of use together, they have different modes of operation, they have different functions, and they have different effects. One would not have to practice the various methods at the same time to practice just one method alone.

The search for each of the above inventions is not co-extensive particularly with regard to the literature search. Further, a reference which would anticipate the invention of one Group would not necessarily anticipate or even make obvious another Group. Finally, the consideration for patentability is different in each case. Thus, it would be an undue burden to examine all of the above inventions in one application.

Because these inventions are distinct for the reasons given above and the search required for each Group is not necessarily required for the other Groups, restriction for examination purposes as indicated is proper.

Applicant is advised that the response to this requirement, to be complete, must include an election of the invention to be examined even though the requirement be traversed.

No matter which group is elected, a further election of species is required. This application contains claims directed to the following patentably distinct species: the many and multiple compositions to be used (e.g., YG-Product, YGG-Product, Purified Leukocyte Dialysate Subfraction or a combination thereof), the many and multiple

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chronic inflammation conditions to be treated (e.g., hypertension, hypercholesterolemia, hypertriglyceridemia, obesity or a combination thereof), the many and multiple metabolic syndrome diseases to be treated (e.g., obesity, insulin resistance, hypertension, dyslipidemia, impaired glucose tolerance or a combination thereof). The species are independent or distinct because they are drawn to different compositions and diseases or symptoms thereof which would require separate consideration and/or search.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species [i.e., elect a single and specific composition or combination thereof, and depending on the group elected, elect also a single and specific chronic inflammation condition or combination thereof to be treated and/or a single and specific symptom of metabolic syndrome disease/symptom or combination thereof to be treated. For example, if Group I is elected, elect also a composition such as YG-product, a chronic inflammation disease such as hypertryglyceridemia and metabolic syndrome such as obesity] for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, 1-18 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations

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of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species.

MPEP § 809.02(a).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

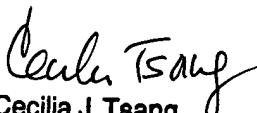
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marcela M. Cordero Garcia whose telephone number is (571) 272-2939. The examiner can normally be reached on M-Th 7:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia J. Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Marcela M Cordero Garcia, Ph.D.
Patent Examiner
Art Unit 1654

MMCG 05/06


Cecilia J. Tsang
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